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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/758,962	01/09/2001	Simon Santa-Cruz	00801.0192.NPUS00	9671
22798	7590	10/06/2003	EXAMINER	
QUINE INTELLECTUAL PROPERTY LAW GROUP, P.C. P O BOX 458 ALAMEDA, CA 94501			QIAN, CELINE X	
			ART UNIT	PAPER NUMBER
			1636	26

DATE MAILED: 10/06/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/758,962

Applicant(s)

SANTA-CRUZ ET AL.

Examiner

Celine X Qian

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 07 July 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-5, 7-30, 38 and 53-56 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 38 is/are allowed.
- 6) ☒ Claim(s) 1-5, 7-30 and 53-56 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 January 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 16, 18.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

### **DETAILED ACTION**

Claims 1-5, 7-30, 38 and 53-56 are pending in the application.

This Office Action is in response to the Amendment filed on 7/7/03.

#### ***Response to Amendment***

The Objection to claim 4 has been withdrawn in light of Applicants' amendment of the claims.

The rejection of claims 18 and 38 under 35 U.S.C 112 1<sup>st</sup> paragraph has been withdrawn in light of Applicants' submission of the ATCC receipt for biological deposit.

The rejection of claims 2-5, 7, 14 and 26-28 under 35 U.S.C.112 2<sup>nd</sup> paragraph has been withdrawn in light of Applicants' amendment of the claims.

The rejection of claims 1-3, 5, 9-11 and 30 under 35 U.S.C.102 (b) has been withdrawn in light of Applicants' amendment of the claims.

The rejection of claims 3 and 4 under 35 U.S.C.112 1<sup>st</sup> paragraph is maintained for reasons set forth of the record mailed on 2/3/03 and further discussed below.

The rejection of claims 6-8, 12-17 and 19-29 is maintained under 35 U.S.C 103 (a) for reasons set forth of the record mailed on 2/3/03 and further discussed below.

Claims 1-3, 5, 9-11, 18, 30 and 53-56 are rejected under 35 U.S.C.103 (a) for reasons discussed below.

#### ***Response to Arguments***

##### ***Claim Rejections - 35 USC § 112***

Claims 3 and 4 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not

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described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In response to this rejection, Applicants argue that the specification describes IRES from different species that can direct mRNA translation. Applicants also argue that many IRES have been identified and fully sequenced at the time of filing. Further, Applicants argue that the specification describes IRES comprises different lengths and the exact boundaries of each are variable. Applicants thus conclude that the description is sufficient for the claimed invention.

Applicants' argument has been fully considered but deemed unpersuasive. As discussed in the previous office action, the specification needs to describe a representative of species by their complete structure or other identifying characteristics. Although many IRES were known at the time of filing, each distinct IRES (from different species or variants) has its own unique structure (nucleotide sequence). The specification fails to disclose what is the core structure that is shared by these naturally occurring IRES and fragments for its function. Moreover, the specification fails to disclose any specific fragment(s) of said Tobamovirus IRES that is able to direct translation *in vitro*. It is unclear what is the size and which part of the Tobamovirus IRES (SEQ ID NO:1) sequence is necessary for its function. Thus, the structure function relationship of the IRES is missing. Therefore, the written description requirement is not met.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 6-8, 12-17, 19-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Santa Cruz et al. (1996, PNAS, Vol 93, pp. 6286-6290), in view of Ivanov et al.

In response to this rejection, Applicants argue that the claimed invention is not obvious in view of the cited references for lack of motivation and expectation of success. Applicants argue that the motivation of increase expression is not sufficient for support the obviousness rejection and neither references are cited for the motivation to combine. Further, Applicants argue that one of ordinary skill of art would not have reasonable success to combine the teaching and reach the claimed invention because the two references teaches two different system (*in vitro* vs. *in vivo*). Applicants thus conclude that the invention is not obvious.

The above argument has been fully considered but deemed not persuasive. The cited references render the invention obvious for reasons discussed in detail in the previous office action (paper no. 14). Applicants have not provided specific reason as to why the purpose of increase expression of the second protein is not a sufficient motivation to combine the references. In response to applicant's argument that there is no suggestion to combine the references because neither references were cited for such motivation, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, it is obvious to one of

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ordinary skill of art to insert the IRES to increase the expression of the second protein, thus for increased expression of the coat protein, and better assembly of the viron. Therefore, the motivation to combine the references is present.

In response to Applicants' argument in regard to lack of expectation of success, Applicants are reminded that the claimed invention is a viral vector comprising viral ORF, IRES and a peptide of interest, the claims do not recite expression of the peptide of interest or the viral ORF *in vitro* or *in vivo*. Thus, it does not matter whether the expression system used in two references are different. As such, there is a reasonable expectation of success for making a vector comprising the claimed IRES. Therefore, the claimed invention is obvious in view of the teaching of Ivanov et al. and Santa Cruz et al.

***New Grounds of Rejection Necessitated by Applicants' Amendment***

Claims 1-3, 5, 9-11, 18, 30 and 53-56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ivanov et al., in view of Santa Cruz et al.

The teaching of Ivanov et al. was discussed in detail in the previous office action (page 7). However, Ivanov et al. do not teach a plant viral vector comprising an IRES, an ORF encoding a peptide of interest and an ORF encoding a viral protein.

The teaching of Santa Cruz et al. was discussed in detail in the previous office action (page 8-9). Further, Santa Cruz et al. teach that plant virus-based vectors can be used for different purposes including investigating viral pathology in plant and producing peptide in plants (see page 6286, 1<sup>st</sup> col., 1<sup>st</sup> paragraph).

It would have been obvious to one of ordinary skill or art to make a plant viral vector comprising an IRES, and ORF encoding a peptide of interest and an viral ORF as taught by

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Ivanov et al. The ordinary artisan would have been motivated to make the plasmid vectors taught by Ivanov et al. into a plant viral vector because plant viral vectors' can be used for different purposes including direct protein expression in plant and investigating viral pathology in plant. The level of art in the molecular cloning is high. Absent evidence to the contrary, one of ordinary skill of art would have reasonable expectation of success to clone the polynucleotide comprising IRES, viral ORF and ORF of interest into a plant viral vector as taught by Santa Cruz et al. Therefore, the invention would have been obvious to one of ordinary skill of art at the time the invention was made.

### *Conclusion*

Claim 38 is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celine X Qian whose telephone number is 703-306-0283. The examiner can normally be reached on 9:00-5:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel Ph.D. can be reached on 703-305-1998. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Celine Qian, Ph.D.

*Anne-Marie Falk*

ANNE-MARIE FALK, PH.D  
PRIMARY EXAMINER